

Application No. 09/720,278  
Response to Office Action dated December 14, 2006  
Paper dated May 24, 2007  
Attorney Docket No. 0702-002214

Response Under 37 CFR 1.116  
Expedited Procedure  
Examining Group 1600

### REMARKS

Claims 1, 10-13, and 15 have been amended herewith. Independent claims 1 and 11 have been amended to specify that the polycationic peptide or protein is bovine lactoferrin. This amendment has been made without prejudice to the filing of one or more continuation applications directed to the other polycationic peptide or protein species disclosed in the present specification. However, it is believed that the current scope of the main claim can be seen to have been appropriately enabled for the treatment of *Candida* and that this showing can be acknowledged without prejudice. The addition of fluconazole to the medicament appears in claim 10, but as the Figures of the application illustrate, new and unexpected results inure to the use of the bovine lactoferrin alone. Therefore it is believed that the enablement rejection is in condition to be withdrawn.

Regarding the asserted obviousness rejections over Wakabayashi of record taken in view of Steinberg of record, one skilled in the art cannot piece the invention together from Wakabayashi and Steinberg even with the benefit of hindsight. It is likely that the Examiner misread page 38 of Steinberg, as explained as follows. Wakabayashi is cited as teaching the application of lactoferrin but admittedly does not teach the claimed buffer or pH. Example 1 of Steinberg (see top of page 38) is directed to the synthesis of peptides PG-1 and OM-3 and thus is not directed to the synthesis of bovine lactoferrin. (In fact, bovine lactoferrin is not synthesized at all for the purposes of the present invention, but is derived from a bovine source.) In section 1.2 of Example 1, Steinberg discusses dissolving an intermediate (crude) peptide in DMSO and that the solution has a pH between 7.0 and 7.2 for this intermediate, prior to Steinberg's discussing how to finish the peptide into something that could be administered to a patient by eluting it with buffer to create a "lyophilized to dryness" peptide. Dry peptide is no longer buffered. It is therefore apparent that any teaching relying on Steinberg is directed to using buffers to make dry eluted peptide, although not necessarily bovine lactoferrin, which is mentioned on page 5 in a more general context. Most importantly, when the peptide(s) of Steinberg are actually formulated for topical gel formulation, (See Example 2, again referring to OM-3 peptide) buffer is not added to the formulation at all, so Steinberg cannot suggest the critical presence of buffer in claims 1 and 11 and all claims dependent therefrom. In other words, Steinberg cannot supply the missing teaching that a specified amount of buffer can maintain the pH of treatable tissue within a pre-selected range, and achieving a certain pH in manufacturing an intermediate does not

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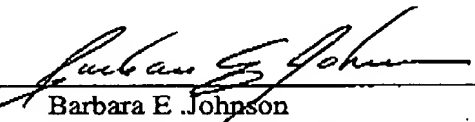
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suggest the optimal tissue pH for treatment at all. The cited references within Wakabayashi do not supply the missing buffer/pH range teaching either, nor would any general knowledge in the art inspire it, because the references do not teach or suggest the recited buffer and pH or even identify that tissue pH might be a consideration in developing a *Candida* treatment.

Applicants herewith request entry of the above claim amendments and allowance of the application, if possible by June 14, 2007. An early Notice of Allowance is respectfully requested.

Respectfully submitted,

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